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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,919

04/16/2004

Alexander Deiters

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09/03/2009

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

09/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,919	DEITERS ET AL.	
	Examiner	Art Unit	
	KAGNEW H. GEBREYESUS	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-54, 56-59 and 62-64 is/are pending in the application.
- 4a) Of the above claim(s) 62 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/are allowed.
- 6) ☒ Claim(s) 53-54, 56-59, 63-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2009 has been entered. Claims 1-51 are cancelled. Claims 53, 56, 58, 62-64 are amended. Claims 52-54, 56-59, 63-64 are present for examination.

Applicants argue that claim 62 should not be withdrawn because claim 53 includes an O-RS that preferentially aminoacylates O-tRNA with p-propargyloxy-phenylalanine and the claim further define the ORS as SEQ ID NO: 54-63.

Applicant's argument has been carefully considered but not found persuasive for two reasons.

1) The previous Office action does not state that claim 53 was allowable. This is because the structure of conservative variants of SEQ ID NO: 48-53 with the desired function were not described in the specification.

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2) Furthermore, as claimed in previous claim 53, the ORS of SEQ ID NO: 48-53 applied for both part (i) and (ii) of the claim. The Office Action was based on the search of the sequences of SEQ ID NO: 48-53.

The instant claims states that the O-RS of SEQ ID NO: 48-53 are specifically used for aminoacylating an O-tRNA with a p-azido-phenylalanine while newly introduced SEQ ID NO: 54-63 appear to be specific for p-propargyloxy-phenylalanine.

However the two sets of sequences are structurally and/or functionally different. Searching additional sequences would impose an undue search burden to the examiner and to the Patent Office. Thus claim 62 will remains withdrawn from consideration. Claims 52-54, 56-59, 63-64 are present for examination.

Sequence Compliance

This application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. In particular, 37 CFR 1.821 (d) states: "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application".

In the instant case, the requirements are not met because in claims 53 (ii), 54-56-59, 64, the variants of SEQ ID NO: 48-53 further having at least two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli*

are not assigned sequence identifiers in the text of the description or in the claims.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately using SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. § 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO. Appropriate correction/clarification is required.

Maintained - Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-54, 56-59, 63-64 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the claim to encompass all possible variants of SEQ ID NO: 48-53 with 90% identity to any naturally occurring tyrosyl tRNA synthetase and

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comprising two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli*.

Furthermore part (i) of claim 53 now appears to include O-RS molecules specific for p-propargyloxy-phenylalanine where the structure of such ORS are not described.

The specification teaches a method of producing in a eukaryotic cell a protein comprising an unnatural amino acid where the O-RS of SEQ ID NO: 48-53 that preferentially aminoacylate a structurally undefined corresponding O-tRNA with para-azido-L-phenylalanine where used. Furthermore the specification teaches said protein comprising the p-azidophenylalanine can be reacted to the unnatural amino acid p-propargyloxy-phenylalanine through a [3+2] cycloaddition reaction thereby modifying the protein.

However the instant claims are drawn to a eukaryotic cells comprising a genus of O-RS molecules that preferentially aminoacylate structurally undefined O-tRNAs with p-propargylphenylalanines and where said cells further comprise a genus of O-RS molecules comprising SEQ ID NO: 48-53 and variants with 90% comprising two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli* that preferentially aminoacylate structurally undefined O-tRNA molecules with p-azidophenylalanines.

The specification does not teach eukaryotic cells comprising a genus of O-RS molecules with different specificities that are co-expressed and preferentially aminoacylate O-tRNAs (structurally undefined) with p-azidophenylalanines and with p-propargylphenylalanines which are incorporated in a protein.

Furthermore the specification does not teach conservative variants of SEQ ID NO: 48-53 with 90% identity to and comprising two or more variations at positions 37, 126, 182, 183 and 186 relative to the tyrosyl tRNA synthetase of *E. coli*.

While MPEP § 2163 acknowledges that in certain situations “one species adequately supports a genus”, it also acknowledges that “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.” In the instant case the recited genus of ORS encompass species widely variant with respect to their structures, which include all ORS sequences that aminoacylate undefined O-tRNA molecules with a p-propargyloxyphenylalanine and p-azido-L-phenylalanine but also variants of these O-RS molecules as stated above.

However the disclosure of SEQ ID NO: 48-53 is insufficient to be representative of the attributes and features of all species encompassed by the claimed sequence variants because up to 10% variations within the sequence of any ORS molecule can have a profound effect on it's function (both activity and specificity to amino acids). However the specification does not disclose all possible variants with up to 10% variation that retain function.

Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 53-54, 56-59, 63-64 remain rejected under 35 U.S.C. 112, first paragraph since the specification fails to sufficiently describe the claimed invention in such full,

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clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 52-59 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 52-59 of copending Application No. 10/561,121. (PG US 2006/0246509 A1). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Applicants point to the cancellation of claims 52-59 in Application No. 10/561,121. Therefore this rejection is withdrawn.

Claim 52 was provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 123 of copending Application No. 11/978,223. Applicants have agreed to cancel claims 123 in Application No. 11/978,223.

Conclusion: Claims 52 is allowable.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an

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appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee of \$510.00.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAGNEW H. GEBREYESUS PhD whose telephone number is (571)272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kagnew H Gebreyesus/
Examiner, Art Unit 1656

/ANAND U DESAI/
Primary Examiner, Art Unit 1656
August 30, 2009